

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT**IN THE CLAIMS:**

This listing of the claims will replace all prior versions, and listings, of claims in the application:

1-55. (cancelled)

56. (previously presented) A process for preparing an acellular soft tissue graft, comprising:

extracting at least one soft tissue sample with a hypotonic buffered extracting solution to produce extracted tissue;

treating said extracted tissue with a first processing solution to produce a first processed tissue;

washing said first processed tissue, in at least one washing solution comprising water to produce washed tissue; and

storing said washed tissue in a storage solution comprising at least one decontaminating agent and water,

wherein said hypotonic buffered extracting solution comprises at least one nonionic detergent and at least one endonuclease, and said first processing solution comprises at least one anionic detergent.

57. (previously presented) The process of claim 56, wherein said extracting solution has an alkaline pH and a hypotonic osmolality, which is hypotonic to cells in said soft tissue sample.

58. (previously presented) The process of claim 57, wherein said extracting solution comprises at least one of polyoxyethylene alcohol, polyoxyethylene isoalcohol, polyoxyethylene p-t-octyl phenol, polyoxyethylene nonylphenol, polyoxyethylene esters of fatty acids, and polyoxyethylene sorbitol esters.

59. (cancelled)

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

60. (currently amended) The process of claim 56, wherein said first processing solution comprises at least one buffer, ~~wherein said extracting solution~~ has an alkaline pH and a hypertonic osmolality which is hypertonic to cells in said soft tissue sample.

61. (previously presented) The process of claim 60, wherein said first processing solution comprises at least one of sodium dodecylsulphate, sodium dodecylsulphonate, sodium dodecyl-N-sarcosinate, sodium laurylsulfate, and sodium suramin.

62. (currently amended) The process of claim 56, wherein said first processing solution or said extracting solution comprises at least one of a monovalent salt, a divalent salt, and an antimicrobial agent, ~~wherein said first processing solution or said extracting solution is reactive with said anionic detergent.~~

63. (previously presented) The process of claim 56, wherein said storage solution comprises ultrapure, endotoxin-free, water.

64. (previously presented) The process of claim 56, wherein said decontaminating agent comprises at least one antimicrobial agent.

65. (previously presented) The process of claim 64, wherein said decontaminating agent comprises at least one of chlorine dioxide, ethanol, isopropanol, methanol, glycerol, and methylparaben.

66-69. (cancelled)

70. (previously presented) The process of claim 56, wherein said endonuclease is a broad spectrum endonuclease which degrades deoxyribonucleic acids (DNA) and ribonucleic acids (RNA).

71. (previously presented) The process of claim 70, wherein said broad-spectrum endonuclease

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

is a recombinant endonuclease.

72. (cancelled)

73. (previously presented) The process of claim 70, wherein said broad-spectrum endonuclease is present in said hypotonic buffered extracting solution in a concentration sufficient to degrade deoxyribonucleic acids and said ribonucleic acids present in said soft tissue sample.

74. (previously presented) The process of claim 73, wherein said concentration of said broad-spectrum endonuclease is from about 20 IU to about 400 IU per 1 ml volume of tissue.

75. (original) The process of claim 70, wherein an activity of said broad-spectrum endonuclease is enhanced by said one or more nonionic detergents.

76. (previously presented) The process of claim 56, wherein said extracting comprises subjecting said soft tissue sample to a pressure mediated flow of said extracting solution.

77. (cancelled)

78. (previously presented) The process of claim 56, wherein said treating comprises subjecting said extracted tissue to a pressure mediated flow of said first processing solution.

79. (cancelled)

80. (previously presented) The process of claim 56, wherein said washing comprises subjecting said first processed tissue to a pressure mediated flow of said washing solution.

81-85. (cancelled)

86. (previously presented) The process of claim 62, wherein said first processing solution or said

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

extracting solution comprises at least one of sodium chloride, potassium chloride, lithium chloride, calcium chloride, sodium phosphate, calcium hydroxide, potassium sulfate, lithium sulfate, calcium phosphate, potassium phosphate, lithium phosphate, ammonium chloride, magnesium chloride, and calcium sulfate.

87. (previously presented) The process of claim 56, wherein said extracting is carried out for a time period of from about 6 hours to about 24 hours.

88. (previously presented) The process of claim 87, wherein said extracting is carried out for a time period of from about 12 hours to about 16 hours.

89. (previously presented) The process of claim 56, wherein said extracting is carried out at a temperature of from about 4 °C to about 42 °C.

90. (previously presented) The process of claim 89, wherein said extracting is carried out at a temperature of from about 20 °C to about 27 °C.

91-95. (cancelled)

96. (previously presented) The process of claim 58, wherein said nonionic detergents are at a concentration of from about 0.001% (w:v) to about 10% (w:v).

97. (previously presented) The process of claim 96, wherein said nonionic detergents are at a concentration of from about 0.1% (w:v) to about 2% (w:v).

98. (previously presented) The process of claim 61, wherein said anionic detergents are at a concentration of from about 0.001% (w:v) to about 4% (w:v).

99. (previously presented) The process of claim 98, wherein said anionic detergents are at a concentration of from about 0.1% (w:v) to about 2% (w:v).

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

100-101. (cancelled)

102. (previously presented) The process of claim 86, wherein said first processing solution or said extracting solution comprises at least one of calcium chloride, calcium hydroxide, magnesium chloride, lithium chloride, potassium chloride, and sodium chloride.

103-107. (cancelled)

108. (previously presented) An acellular tissue graft prepared by the process of claim 56, wherein said anionic detergent is SDS and wherein the washed tissue comprises ~~is present at a concentration of about 0.001 wt %~~ SDS.

109. (previously presented) A process for preparing an acellular soft tissue graft comprising:

- extracting at least one soft tissue sample with an alkaline hypotonic buffered extracting solution to produce extracted tissue;
- treating said extracted tissue with a treating solution comprising a hypertonic salt solution to produce a treated tissue;
- treating said treated tissue, with a first processing solution to produce a first processed tissue;
- treating said first processed tissue with a second treating solution to produce a second treated tissue;
- washing said second treated tissue, in at least one washing solution comprising water to produce washed tissue; and
- storing said washed tissue in a storage solution comprising at least one decontaminating agent and water,

wherein said extracting solution comprises at least one nonionic detergent and at least one endonuclease, said first processing solution comprises a first hypertonic salt solution and at least one anionic detergent, and said second processing solution comprises a second hypertonic salt solution.

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

110-120. (cancelled)

121. (previously presented) An acellular tissue graft prepared by the process of claim 56 or claim 109.

122. (previously presented) The tissue graft of claim 121, wherein the graft is essentially non-immunogenic.

123. (previously presented) The tissue graft of claim 121, wherein the graft has essentially the same tensile properties as the soft tissue sample.

124. (previously presented) The tissue graft of claim 121, wherein the tissue sample is a vein, an artery, or a heart valve.

125. (previously presented) The tissue graft of claim 121, wherein the tissue sample is a ligament or a tendon.

126. (previously presented) The tissue graft of claim 121, wherein the tissue sample is fascia, dura mater, pericardium or skin.

127. (previously presented) The tissue graft of claim 121, wherein the graft remains acellular post implantation.

128. (previously presented) The tissue graft of claim 121, wherein the graft remains acellular for at least 6 months post implantation.

129. (previously presented) The tissue graft of claim 121, wherein the graft re-endothelializes on a luminal surface 3 to 6 months post implantation.

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

130. (previously presented) The tissue graft of claim 121, wherein the tissue sample is cartilage.

131. (currently amended) An acellular tissue graft, comprising a soft tissue sample substantially free from cellular elements and calcium ion precipitated anionic ~~nonionic~~ detergent, produced by the process of claim 56 or claim 109, wherein recellularization of said acellular tissue graft *in vivo* or *in vitro* is retarded.

132. (previously presented) The tissue graft of claim 131, wherein the tissue sample is cartilage.

133. (new) The tissue graft of claim 121, wherein the graft comprises at least 1.0 μ mole calcium ion precipitated anionic detergent/mg wet weight of tissue.

134. (new) The tissue graft of claim 121, wherein the washed tissue comprises from about 0.1 wt% to about 10 wt% calcium ion precipitated anionic detergent.

135. (new) The tissue graft of claim 121, wherein the washed tissue comprises less than 20 wt% precipitated anionic detergent.

136. (new) The tissue graft of claim 121, wherein the washed tissue comprises from about 0.2 wt% to about 2.0 wt% precipitated anionic detergent.

137. (new) The process as in claim 56 or 109, wherein the washed tissue comprises at least 1.0 μ mole calcium ion precipitated anionic detergent/mg wet weight of tissue.

138. (new) The process as in claim 56 or 109, wherein the washed tissue comprises from about 0.1 wt% to about 10 wt% calcium ion precipitated anionic detergent.

139. (new) The process as in claim 56 or 109, wherein the washed tissue comprises less than 20 wt% precipitated anionic detergent.

DOCKET NUMBER: 95176562-004002 (64230-00004USD1)
PATENT

140. (new) The process as in claim 56 or 109, wherein the washed tissue comprises from about 0.2 wt% to about 2.0 wt% precipitated anionic detergent.